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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/178,126

Applicant(s)

STIVLAND ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 49-74 and 101-109 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49-74 and 101-109 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 49-56, 61-64, 67, 69, 73, 101-106 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view Fontirroche et al., 5,538,510.

Sirhan et al. discloses the invention substantially as claimed. More specifically, as to claims 49 and 101, Sirhan et al. discloses a first tube (32 and 47) including an inflation lumen (36, see col. 5, lines 56-57) in fluid communication with a dilatation balloon (37), an inside wall surface, and an outside wall surface, said first tube having an orifice (42) in a proximal portion of said first tube; a second tube (33 and layer overlying 47 near orifice 42 in fig. 16) inserted through, and extending distally from said orifice inside said inflation lumen, said second tube having a length, a lumen therethrough, a proximal portion, an inside wall surface and an outside wall surface, see Figure 16; said second tube inside wall surface being formed of a second, lubricous material for a majority of said second tube length, said first tube wall having a layer of a

first, flexible material extending for a majority of said first tube length, said first material being different from said second material (column 9, lines 46-53.)

Sirhan et al. discloses in figure 16 a portion of the second tube (i.e., layer overlying 47 near orifice 42 in fig. 16) overlaying the first tube (32 and 47), but does not disclose how they are bonded together. More specifically, Sirhan et al. does not teach a bonding region wherein said second tube outside wall surface is bonded to said first tube outside wall surface by re-flow of the first and second tube outside wall surfaces.

However, Sirhan et al. teaches that the inner tubular member (33) and outer tubular member (34) may be secured together by heat or laser bonding, heat shrinking the outer tube onto the inner tube or other suitable means (col. 3, lines 21-23; see also col. 7, line 59 – col. 8, line 16.) Although, Sirhan et al. does not specifically disclose how the layer overlying (47) near orifice (42) in figure 16 is bonded to portion (47) of first tube, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use heat bonding (i.e., re-flow) between the two tube layers because Sirhan et al. teaches that heat bonding provides the advantage of securing two layers together, such as the layers at issue.

Also, Sirhan et al. does not disclose a tie-layer disposed between the inside and outside layers (of the first tube, with respect to independent claim 49, and of the second tube, with respect to independent claim 101), wherein said intermediate tie-layer is disposed at an angle relative to a tube wall of said first tube.

However, Fontirroche discloses a tie-layer, comprising Plexar™ for example, may be used to bond together dissimilar outer plastic layers, see column 2, lines 35-38,

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including plastics that are normally sealingly incompatible with each other (col. 3, lines 9-10). Moreover, Fontirroche discloses that the chemical bonding between two catheter layers can be subsequently heat treated, see column 3, lines 17-20. It would have been obvious to one of ordinary skill in the art at the time the invention was made to bond the plastic layers of the Sirhan et al. catheter by using Plexar because Fontirroche teaches that Plexar provides the advantage of bonding dissimilar plastic catheter layers including plastics that are normally sealingly incompatible with each other.

Moreover, the bonding portion, i.e., the tie-layer portion, in the Sirhan et al. catheter is considered to be disposed between a proximal portion and a distal portion of a tube wall of said first tube, as claimed by Applicant. (Applicant has not specifically defined where the proximal portion and distal portion begins and ends.)

Also, the tie-layer is considered to be disposed at an angle relative to said tube wall. (Applicant has not specifically defined whether the angle is 90 degrees or 180 degrees, for example.)

As to claim 104, the intermediate layer of the second tube is considered to be bond-compatible with both the inner layer lubricious material and the outer layer material (the Office notes that Applicant has not recited the type of bond.)

As to the following claims, Sirhan et al. discloses the limitations as follows.

As to claim 50, said bonding region is proximate said orifice, see column 5, lines 52-56, and see Figure 6.

As to claim 51, said bonding region includes bonding between said first tube inside surface and said second tube outside surface distal of said orifice, see column 3, lines 17-23.

As to claim 52, said second tube inside and outside wall surfaces are formed of said second material, see column 9, lines 46-53.

As to claim 53, said second tube wall is formed of substantially said second material therethrough, see column 9, lines 46-53.

As to claim 54, said first tube inside surface is formed of said second material proximate said bonding region, see column 9, lines 46-53.

As to claim 55, said first tube has said second material disposed over most of said first tube inside surface proximate said bonding region and distal of said bonding region, see column 9, lines 46-53.

As to claims 61-64, Sirhan et al. disclose that the catheter shaft, including the inner and outer tubular members may be made from polymeric materials such as polyethylene, polyamide, etc and other suitable polymeric materials, see column 9, lines 46-53.

As to claim 102, the outer layer of the second tube comprises a material that is bond-compatible with the first tube first material. (The Office notes that the claim does not recite the type of bond.)

As to claim 103, the outer layer of the second tube is also formed of the first tube first material (col. 9, lines 46-53.)

As to claim 105, the second tube comprises a proximal portion (the layer overlying 47) disposed proximally of the first tube orifice and a distal portion (33) disposed distally of the first tube orifice, within the first tube inflation lumen.

As to claim 106, the bonding region (the layer overlying 47) in which the second tube outside wall surface is bonded to the first tube outside wall surface by re-flow of the first and second tube outside wall surfaces corresponds to the proximal portion of the second tube (see fig 16).

As to claim 109, the second tube inner layer comprises polyethylene 9col. 9, lines 48-50.)

2. Claims 57, 66, 68, 70, 74, 107 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view Fontirroche et al., 5,538,510, as applied to claims 56, 65, 69, 71, 73 above, and further in view of Berg et al., 5,792,116.

Sirhan et al. in view of Fontirroche et al. discloses the invention substantially as claimed, see above with respect to claim 56. More specifically, Sirhan discloses that polymeric materials including polyethylene may be used to form the inner or outer tubular members, see column 9, lines 46-53. However, Sirhan et al. in view of Fontirroche et al. does not disclose an outside layer of PEBA.

Berg et al. however discloses a catheter formed from three layers, the third, outer layer being commonly formed of polyether block amide (i.e., PEBA) to provide stability and support during treatment procedures (column 6, lines 8-11). It would have been

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obvious to one of ordinary skill in the art at the time the invention was made to use PEBA, as taught by Berg et al., as the polymeric material to form the outside layer in the Sirhan et al. in view of Fontirroche et al. device, because Berg et al. teaches that PEBA provides the advantage of stability and support during treatment procedures.

3. Claims 58, 59, 65 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view Fontirroche et al., 5,538,510, and further in view of Javier, Jr. et al., 6,093,177.

Sirhan et al. in view of Fontirroche et al. disclose the invention substantially as claimed (see above), except for the first tube having an inside surface formed of said second material proximate said bonding region and said inside surface formed of said first material distal of said bonding region.

However, Javier, Jr. et al. discloses that relative flexibility or the inverse stiffness of the various shaft sections of a catheter may be achieved by selecting different materials. "[T]he material used in the intermediate shaft section may be inherently more flexible than a different material used in the proximal or distal shaft sections", see column 2, lines 5-15. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide different materials on different shaft sections of the Sirhan et al. catheter in order to achieve the desired flexibility of the catheter shaft sections as may be necessary for a particular treatment of a patient



4. Claims 60 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view of Javier, Jr. et al., 6,093,177, further in view of Fontirroche et al., 5,538,510, as applied to claim 59, and further in view of Berg et al., 5,792,116.

Although Sirhan in view of Javier and further in view of Fontirroche disclose the invention substantially as claimed, they however do not disclose the first tube being formed of PEBA distal of said tie-layer.

Berg et al. however discloses a catheter formed from three layers, the third, outer layer being commonly formed of polyether block amide (i.e., PEBA) to provide stability and support during treatment procedures (column 6, lines 8-11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use PEBA, as taught by Berg et al., as the polymeric material to form the outside layer in the Sirhan et al. in view of Fontirroche et al. device, because Berg et al. teaches that PEBA provides the advantage of stability and support during treatment procedures.

5. Claims 75-82, 87-90, 93, 95 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., 5,743,875, in view Fontirroche et al., 5,538,510, and further in view of Ressemann et al., 5,571,087.

Sirhan et al. discloses the invention substantially as claimed. More specifically Sirhan et al. discloses a first tube (32) including an inflation lumen (36 and proximal portion of 37) in fluid communication with a dilatation balloon (distal portion of 37), an inside wall surface, and an outside wall surface, said first tube having an orifice (42) in a

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proximal portion of said first tube; a second tube inserted through, and extending distally from said orifice inside said inflation lumen, said second tube having a length, a lumen therethrough, a proximal portion, an inside wall surface and an outside wall surface, see Figure 16; and a bonding region wherein said second tube outside wall surface is bonded to said first tube outside wall surface by re-flow of the first and second tube outside wall surfaces, see column 3, lines 17-23, and column 7, line 59 – column 8, line 16, said second tube inside wall surface being formed of a second, lubricous material for a majority of said second tube length, said first tube wall having a layer of a first, flexible material extending for a majority of said first tube length, said first material being different from said second material, see column 9, lines 46-53.

However, Sirhan et al. does not disclose a tie-layer disposed between the inside and outside layers, wherein said intermediate tie-layer is disposed at an angle relative to a tube wall of said first tube.

Fontirroche discloses a tie-layer, comprising Plexar™ for example, may be used to bond together dissimilar outer plastic layers, see column 2, lines 35-38. Moreover, Fontirroche discloses that the chemical bonding between two catheter layers can be subsequently heat treated, see column 3, lines 17-20. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to bond the plastic layers of the Sirhan et al. catheter by using Plexar as a tie-layer to bond the plastic layers, as taught by Fontirroche.

Also, Sirhan et al. does not teach a core wire extending distally from the third tube into the first tube.

Ressemann et al. however teaches a catheter (20) having a section (22) being relatively stiff and the distal shaft section (23) being relatively flexible, the configuration of which will tend to bend or buckle in the relatively flexible area as an attempt is made to advance the catheter (2) through a vasculature, the catheter tending to kink at the transition section. Ressemann et al. teaches that a core wire (25), see column 7, lines 26-27, in the catheter provides two functions: to provide axial or column strength to the distal shaft section (24); and to prevent kinking of the distal shaft section (24). It would have been obvious to provide a core wire, as taught by Ressemann et al., in the Sirhan et al.-in-view-of-Fontirroche device in order to provide the advantage of axial strength to the distal shaft section, and/or to prevent kinking of the distal shaft section, which may comprise a different material from a proximal section.

As to the limitations in the following claims, Sirhan et al. discloses the limitations as follows. As to claim 76, said bonding region is proximate said orifice, see column 5, lines 52-56, and see Figure 6.

As to claim 77, said bonding region includes bonding between said first tube inside surface and said second tube outside surface distal of said orifice, see column 3, lines 17-23.

As to claim 78, said second tube inside and outside wall surfaces are formed of said second material, see column 9, lines 46-53.

As to claim 79, said second tube wall is formed of substantially said second material therethrough, see column 9, lines 46-53.

As to claim 80, said first tube inside surface is formed of said second material proximate said bonding region, see column 9, lines 46-53.

As to claims 81, 89, said first tube has said second material disposed over most of said first tube inside surface proximate said bonding region and distal of said bonding region, see column 9, lines 46-53.

As to claims 83, 87, 88, 90, the catheter shaft, including the inner and outer tubular members may be made from polymeric materials such as polyethylene, polyamide, etc and other suitable polymeric materials, see column 9, lines 46-53.

The third tube, the first tube being disposed distal of the third tube, is disclosed. (The third tube is considered to be a proximal section of said first tube, or alternatively, a proximal section of said second tube.)

6. Claim 83, 94, 96 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., in view Fontirroche et al., 5,538,510,, and further in view of Ressemann et al., and further in view of Berg et al., 5,792,116. Sirhan et al., Fontirroche et al., and Ressemann et al. disclose the invention substantially as claimed (see above), except for the outside layer being comprised of PEBA.

Berg et al. however discloses a catheter formed from three layers, the third, outer layer being commonly formed of polyether block amide (i.e., PEBA) to provide stability and support during treatment procedures (column 6, lines 8-11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use PEBA, as taught by Berg et al., as the polymeric material to form the outside layer in the

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Sirhan et al. in view of Fontirroche et al. device, because Berg et al. teaches that PEBA provides the advantage of stability and support during treatment procedures.

7. Claims 84, 85, 91 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., in view Fontirroche et al., 5,538,510, in view of Ressemann et al., and further in view of Javier, Jr. et al., 6,093,177. Sirhan et al., Fontirroche et al., and Ressemann et al. disclose the invention substantially as claimed (see above), except for the first tube having an inside surface formed of said second material proximate said bonding region and said inside surface being formed of said first material distal of said bonding region.

However, Javier, Jr. et al. discloses that relative flexibility or the inverse stiffness of the various shaft sections of a catheter may be achieved by selecting different materials. "[T]he material used in the intermediate shaft section may be inherently more flexible than a different material used in the proximal or distal shaft sections", see column 2, lines 5-15. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide different materials on different shaft sections of the Sirhan et al. catheter in order to achieve the desired flexibility of the catheter shaft sections as may be necessary for a particular treatment of a patient

8. Claims 86, 92 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al., in view of Fontirroche et al., 5,538,510., further in view

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of Ressemann et al., further in view of Javier, Jr. et al., 6,093,177, and further in view of Berg et al., 5,792,116.

Although Sirhan in view of Fontirroche in view of Ressemann et al. and further in view of Javier, Jr et al. disclose the invention substantially as claimed, they however do not disclose the first tube being formed of PEBA distal of said tie-layer.

Berg et al. however discloses a catheter formed from three layers, the third, outer layer being commonly formed of polyether block amide (i.e., PEBA) to provide stability and support during treatment procedures (column 6, lines 8-11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use PEBA, as taught by Berg et al., as the polymeric material to form the outside layer in the Sirhan et al. in view of Fontirroche et al. device, because Berg et al. teaches that PEBA provides the advantage of stability and support during treatment procedures.

### ***Response to Arguments***

Applicant's arguments have been considered but are not persuasive for the following reasons.

The Office has stated that the first tube is considered to be at (32 and 47) and the second tube is considered to be at (33 and layer overlying 47 near orifice 42 in fig. 16).

Applicant stated that differing cross-hatching patterns are employed to indicate that different elements are formed of differing materials, or at least that different

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elements are in fact different. Applicant asserts that one of ordinary skill in the art will recognize that in figure 16 of Sirhan et al. the cited layer overlying element 47 has a cross-hatching pattern that matches the cross-hatching pattern shown in element 32, and thus the cited layer overlying element 47 is in fact part of element 32.

While it is true that different cross-hatching is used for element 32 and the overlying element 47, both elements however are considered the claimed second tube. No recitations in Applicant's claims preclude this interpretation.

Applicant also argues that one of skill in the art will recognize that the catheter shown in figure 16 is formed by forming aperture 42 within element 32, and then inserting element 33 into aperture 42. Applicant argues that there is no portion of element 33 which extends proximally of aperture 42 and therefore no portion of element 33 can be considered as positioned such that an outer surface of element 33 could be bonded to an outer surface of element 32 (or element 47). Applicant states that as noted above, the portion cited by the Examiner as extending proximally of aperture 42 is in fact part of element 32. This argument is not persuasive because Applicant is assuming that only element 32 can be considered the claimed second tube. The Office considers the overlying element 47 to be part of the second tube. Also, with respect to Applicant assertions as to how one of skill in the art will recognize how the catheter of figure 16 of Sirhan et al. is formed, the Office notes that regardless of how the catheter may have been constructed, if the prior art discloses the elements of the device, then the prior art meets the claim.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



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10/17/05